IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

UNITED STATES OF AMERICA, Plaintiff, v. BEN VENUE LABORATORIES, INC., a corporation, and GEORGE P. DOYLE III, KIMBERLY A. KELLERMANN, and DOUGLAS A. RICH, individuals, Defendants.	)	CIVIL NO.

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, United States of America, by its undersigned attorneys, respectfully states as follows:

INTRODUCTION

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act ("Act"), 21 U.S.C. § 332(a), to permanently enjoin Ben Venue Laboratories, Inc., a corporation, and George P. Doyle III, Kimberly A. Kellermann, and Douglas A. Rich, individuals (collectively, "Defendants") from violating: (a) 21 U.S.C. § 331(a) by introducing, delivering, and/or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); and (b) 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and over all parties in this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

DEFENDANTS

4. Ben Venue Laboratories, Inc. ("BVL") is a corporation that manufactures, processes, packs, labels, holds, and distributes drugs from its establishment located at 300 Northfield Road, Bedford, Ohio ("BVL Facility"), within the jurisdiction of this Court. BVL manufactures drugs under its own label, Bedford Laboratories, and as a contract manufacturer. BVL was incorporated in Delaware in 1998 and is a wholly-owned subsidiary of Boehringer Ingelheim USA Corporation, a subsidiary of the German company, Boehringer Ingelheim GmbH.

5. George P. Doyle III is the President and Chief Executive Officer of BVL, and has held these positions since August 2011. Mr. Doyle is responsible for and has final authority over all of BVL's operations including, but not limited to, the manufacture, processing, packing, labeling, holding, and distribution of drugs at and/or from the BVL Facility. He is responsible for ensuring that BVL's methods used in, and the facilities and controls used for, the manufacture, processing, packing, labeling, holding, and distribution of drugs are in compliance with the current good manufacturing practice ("CGMP") requirements. Mr. Doyle performs his duties at the BVL Facility, within the jurisdiction of this Court.

6. Kimberly A. Kellermann is the Vice President of Operations for BVL, and has held this position since October 2011. Ms. Kellermann is responsible for BVL's drug

manufacturing processes (including sterile filling) and equipment and facility maintenance and sanitation. Ms. Kellermann performs her duties the BVL Facility, within the jurisdiction of this Court.

7. Douglas A. Rich is the Vice President of Quality Operations for BVL, and has held this position since July 2012. Mr. Rich is responsible for quality and compliance operations at the BVL Facility, including, but not limited to, ensuring adequate and timely investigations of product deviations and process validation. Mr. Rich has final decision authority for all drug products released by BVL. Mr. Rich performs his duties at the BVL Facility, within the jurisdiction of this Court.

8. Defendants have been and are now engaged in manufacturing, processing, packing, labeling, holding, and distributing drugs as defined at 21 U.S.C. § 321(g).

9. Defendants manufacture drugs using components that they receive in interstate commerce and introduce finished drugs into interstate commerce for shipment outside of Ohio.

ADULTERATED DRUGS

10. Inspections of the BVL Facility by the United States Food and Drug Administration ("FDA") have established that drugs manufactured by BVL are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, and the facilities and controls used for, the manufacture, processing, packing, labeling, holding, and distribution of drugs and drug components are not in compliance with the CGMP requirements for drugs, *see* 21 C.F.R. pts. 210 and 211.

11. Compliance with the CGMP requirements assures that drugs meet the safety requirements of the Act and have the identity and strength and meet the quality and purity

characteristics that they purport or are represented to possess. FDA regulations, which establish minimum CGMP requirements applicable to human drugs, 21 C.F.R. pts. 210 and 211, require manufacturers to control all aspects of the processes and procedures by which drugs are manufactured in order to prevent the production of unsafe and ineffective products. Drugs not manufactured, processed, packed, or held in conformance with CGMP requirements are deemed adulterated as a matter of law, without any showing of actual defect.

12. During FDA's most recent inspection of the BVL Facility between November 7 and December 2, 2011, FDA investigators documented ten (10) separate deviations from CGMP. The violations observed by FDA investigators during the November - December 2011 inspection include, but are not limited to, the following:

A. Failure of the quality control unit to adequately oversee investigations, to ensure adequate and timely maintenance and qualification of equipment, and to ensure adequate procedures and specifications that affect the identity, strength, quality, and purity of drug products, as required by 21 C.F.R. § 211.22;

B. Failure to establish and follow appropriate written procedures designed to prevent microbial contamination of drug products purporting to be sterile, as required by 21 C.F.R. § 211.113(b);

C. Failure to conduct adequate and timely investigations of improperly validated or qualified equipment and drug products that fail to meet specifications, to determine the root cause of failures or discrepancies, and to extend investigations to other batches of drug products that may have been associated with a specific failure or discrepancy, as required by 21 C.F.R. § 211.192; and

D. Failure to properly clean and maintain equipment to ensure the safety, identity, strength, quality, and purity of drug products, as required by 21 C.F.R. § 211.67.

13. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and delivering for introduction into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), as set forth above.

14. Defendants violate the Act, 21 U.S.C. § 331(k), by causing the adulteration, within the meaning of 21 U.S.C. § 351(a)(2)(B), of articles of drug, as defined by 21 U.S.C. § 321(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce, as set forth above.

PRIOR WARNINGS

15. The deviations observed by FDA during the November - December 2011 inspection were similar to deviations observed by FDA investigators during their many previous inspections of the BVL Facility. Most recently, during FDA's May 2011 inspection, FDA investigators documented forty-eight (48) separate deviations from CGMP including, but not limited to, an inadequate quality control unit, inadequate and untimely investigations, inadequately designed aseptic processing areas, poor employee aseptic practices, failure to prevent microbial contamination of drug products purporting to be sterile, and failure to determine the root cause for microbial contaminants.

16. FDA's long regulatory history of BVL, including thirty-five inspections since 1997, and approximately forty recalls since February 2002 associated with drugs manufactured at the BVL Facility (including ten recalls in 2011 and ten recalls in 2012), reflects a continuing pattern of significant deviations from CGMP. Of these recalls, nine were classified by FDA as

"Class I," meaning that FDA determined that there was "a reasonable probability that the use of . . . a violative product will cause serious adverse health consequences or death." 21 C.F.R. § 7.3(m)(1).

17. BVL's noncompliance has continued despite repeated warnings from FDA regarding their CGMP violations. FDA investigators issued a detailed List of Inspectional Observations, Form FDA-483, to BVL at the conclusion of twenty-four (24) FDA inspections, notifying BVL of the FDA investigators' observations. Each time, the FDA investigators discussed the violations listed in the Form FDA-483s with BVL's management, who typically responded in writing and promised to correct the deficiencies observed by FDA. Nevertheless, FDA investigators have continued to observe significant CGMP violations at subsequent inspections.

18. FDA also issued a Warning Letter to then-President of BVL in November 2007, identifying numerous CGMP violations found during FDA's May - June 2007 inspection. The Warning Letter emphasized the serious nature of the CGMP violations at the BVL Facility and stated that failure to correct the violations could lead to legal action including an injunction. BVL management responded to the Warning Letter in writing in December 2007 and January 2008, and met with FDA in December 2007, promising corrective actions.

19. FDA has participated in numerous conference calls and meetings with BVL management since June 2011, during which FDA has assisted BVL in identifying and prioritizing corrective actions necessary to comply with CGMP.

20. Plaintiff is informed and believes that, unless restrained by this Court, Defendants will continue to violate the Act, 21 U.S.C. §§ 331(a) and (k), in the manner herein alleged.

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Permanently restrain and enjoin Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from manufacturing, processing, packing, labeling, holding, and/or distributing articles of drug, unless and until Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute articles of drug are established, operated, and administered in conformity with the CGMP requirements and the Act, in a manner that has been found acceptable by FDA;

II. Permanently restrain and enjoin Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly doing or causing the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing, delivering, and/or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); and

B. Violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

III. Authorize FDA pursuant to this injunction to inspect Defendants' places of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug to ensure continuing compliance with the Act and the terms

of this injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Award Plaintiff costs and such other equitable relief as the Court deems just and proper.

Dated this 22 day of January, 2013.

Respectfully submitted,

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